



**UNITED STATES DEPARTMENT OF COMMERCE  
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/963,239      | 11/03/97    | ROURE                | 13724-787           |

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QM41/0330

EXAMINER

PEFFLEY, M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 03/30/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/963,239

Applicant(s)

Gough et al

Examiner

Michael Peffley

Group Art Unit

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☒ Responsive to communication(s) filed on Feb 17, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-44 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-44 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's amendments and comments, received February 17, 1999, have been fully considered by the examiner. The following is a complete response to the communication of February 17, 1999

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 remains unclear as to whether or not the energy source is being positively recited as part of the invention: It is noted that line 4 of claim 1 sets forth an antenna ablation device which is "configured to be coupled to an electromagnetic energy source", which indicates the energy source is not to be positively recited as part of the invention. However, the last two lines of claim 1 positively connect a cable between the antenna device and the energy source thereby positively including the energy source as part of the claim. It is also noted that several of the dependent claims recite limitations which would require the energy source to be positively recited as part of the invention. The claims must be clarified to either positively recite the energy source

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in claim 1, or amend claim 1 and the dependent claims so as not to positively recite limitations of the energy source.

It is noted that applicants have not indicated that claim 1 has been amended to overcome the 35 USC 112, second paragraph rejection, nor have applicants traversed the rejection.

***Claim Rejections - 35 USC § 103***

Claims 1-12 and 15-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al ('276) in view of the teaching of Edwards et al ('675).

LeVeen et al disclose a device which comprises a trocar (502) and a multiple antenna ablation device (26) including three or more antennas (24) deployable from the trocar lumen in a lateral direction. Each of the antennas has an ablation surface, and the plurality of antennas are used to create an ablation volume of spheroid shape. The antennas are less rigid than the trocar, and the power range disclosed by LeVeen et al is within the range set forth by the applicant. Further, LeVeen et al teach that the device may be used in either a bipolar or a monopolar mode with the trocar serving as a possible return path.

The only feature not expressly taught by LeVeen et al is the energy delivery surface size which is "sufficient to create a volumetric ablation between the deployed antennas without impeding out a deployed antenna when 5-200 watts of electromagnetic energy is delivered" and the use of an impedance monitoring means. In as much as the LeVeen et al and the applicant's device appear very much similar, the examiner can see no reason why the LeVeen et al device

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would “impede out”. More specifically, there is no specific disclosure in the applicant’s specification of the particular size of the energy delivery surface which prevents this “impeding out” of the electrodes. Moreover, it appears one of ordinary skill in the art would obviously be capable of creating the proper energy surface area to prevent impeding out an antenna without undue experimentation.

Edwards et al teach that it is generally well known to monitor the impedance of a multiple electrode RF ablation device so as to avoid unwanted impedance levels (see column 13, lines 11-13). Such impedance monitoring and feedback means are generally well known in the art. Edwards et al also disclose the use of sensors (i.e. temperature sensors) located on the electrodes and the sheath (see Abstract), as well as a means to provide a fluid to tissue.

Also, while LeVeen et al disclose the use of a trocar to introduce the multiple antenna ablation device, LeVeen et al fail to disclose the specific size of the trocar. The examiner maintains that use of any well known trocar size would have been an obvious design consideration dependent upon the particular procedure as well as the particular antenna device being used.

To have provided the LeVeen et al device with an impedance monitoring and control means to control the delivery of energy to the electrodes to avoid “impeding out” the electrodes would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards et al (‘675)

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***Response to Arguments***

Applicant's arguments with respect to claims 1-44 have been considered but are moot in view of the new ground(s) of rejection.

In particular, it is noted that the Edwards et al ('675) reference fairly discloses an impedance monitoring and control means (as is now set forth in claim 1) used with a multiple needle electrode ablation device similar to the applicant's invention.

***Allowable Subject Matter***

Claims 13 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art fails to disclose a multiple antenna ablation apparatus whereby the multiple antenna extend from holes in the side of the trocar instrument.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Monday through Thursday from 7:00 to 5:30.

In the event the examiner can not be reached or is absent from the Office, the examiner's supervisor, Linda Dvorak, can be reached at (703) 308-0994.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Michael Peffley/mp  
Primary Examiner  
Art Unit 3739  
March 26, 1999

  
MICHAEL PEFFLEY  
PRIMARY EXAMINER  
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